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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,181	12/09/2005	Gitte Juel Friis	P70948US0	1455

136 7590 02/07/2008

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EXAMINER	
EBERHARD, JEFFREY S	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,181	FRIIS ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Eberhard, Ph.D.	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/3/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Fabrication of the device and mode or mechanism of transfer of the active ingredient from the device to the underlying tissue, critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Independent claim 1 recites "a wound care device comprising an active pain killing agent, said device being capable of releasing a pain killing agent to a wound." Further explanation or elucidation of the steps, mechanism, procedure, device or the like embodied in the phrase "capable of releasing" must be provided.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 5 are drawn to a device having specific or maximum absorption. It is not clear whether the absorption to which Applicant refers is from device to skin (*e.g.*, the active pain-killing ingredient), or skin to device (*e.g.*, wound exudate). It is likewise unclear whether the absorption to which Applicant refers is of the pain-killing component or the entire formulated product. The term "substantially non-absorbent" in claim 5 is a relative term which renders the claim indefinite. The term "substantially non-absorbent " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "substantially independent" in claim 6 is a relative term which renders the claim indefinite. The term "substantially independent " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 8-15 and 17-18 are drawn to the extent of bioavailability of the pain-killing component of the instant invention, reciting "at least XX% of the pain killing agent is released during the first YY hours after the application." Applicant fails to particularly point out the nature of the recited "release," whether it might be some sort of controlled release, release from some component of the formulation or matrix, or release from the underlying tissue to which the formulation is applied.

Regarding claim 16, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 29 is rejected under 35 U.S.C. 102(a) as being anticipated by Falk (US 5,910,489).

The instant claim is drawn to a method of treating pain at a wound site using a device comprising an anti-inflammatory pain relieving composition that minimizes systemic uptake of the pain reliever.

Falk teaches a non-steroidal anti-inflammatory pain relieving drug (*e.g.*, NSAID, column 7, line 25) formulated for topical application at the "site of trauma or pathology" (column 7, lines 54-56) such that there is a "lack of blood level of the drug" (column 8, lines 4-10). Falk further teaches that the amount of NSAID delivered topically is less than 2 mg (1% diclofenac in EPDICLO1, column 20, first and last tables) while the lowest "Recommended systemic daily unit dose" for diclofenac is 75 mg (*See* instant specification, Table 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falk (US 5,910,489).

The instant claims are drawn to a wound care device comprising an anti-inflammatory pain relieving agent delivered directly to the wound regardless of the amount of exudate present such that there is no effective systemic concentration of the agent.

Regarding claims 1-3, 7-15 and 19 Falk teaches an anti-inflammatory pain relieving drug (*e.g.*, NSAID, column 7, line 25) formulated for topical application at the "site of trauma or pathology" (column 7, lines 54-56) such that there is a "lack of blood level of the drug" (column 8, lines 4-10). Falk further teaches that the amount of NSAID delivered topically is less than 2 mg (1% diclofenac in EPDICLO1, column 20, first and last tables) while the lowest "Recommended systemic daily unit dose" for diclofenac is 75 mg (*See* instant specification, Table 1). Falk does not teach that "at least 50% w/w of the pain-killing agent is delivered during the first 24 hours after application, but it does teach that 17% is absorbed and therefore delivered[1] (*See* column 21, Table).

The adjustment of particular conventional working conditions (*e.g.*, determining result effective amounts of the ingredients beneficially taught by the cited reference, especially within the broad range recited in claim 1),] as well as affecting desired absorption of active pain-killer,

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[1] [(0.1904 g skin - average top portion x 660 μg/g diclofenac) + (1.2400 g skin – average bottom portion x 169 μg/g diclofenac)]/9.6 cm^2 = 35 μg/cm^2 = diclofenac absorbed.

20 mg gel applied/cm^2 x 1000 μg/mg x (1 mg diclofenac/100 mg gel) = 200 μg/cm^2 diclofenac applied.

35 μg/cm^2 diclofenac absorbed/200 μg/cm^2 diclofenac applied = 0.17

is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the person of ordinary skill in the art at the time the invention was made, and no more than an effort to optimize results.

Regarding claims 4-6, 17 and 18, Examiner takes absorption to refer to absorption of the pain relieving component by the underlying skin. Falk is discussed above, but is silent regarding wound exudate and absorption of the formulated composition. It does address absorption of one part of the formulated composition, the pain-killing component (*e.g.*, diclofenac), by the underlying tissue, and because of its silence concerning wound exudate, a person of ordinary skill in the art would understand that it teaches an invention that is "independent of the amount of wound exudate."

Applicant recites that the device has a maximum absorption of 0.2 g/cm^2 in claim 4, or that it is substantially non-absorbent (claim 5). Falk teaches application of 0.02 g/cm^2 of formulated product (0.0002 g/cm^2 of diclofenac) at column 21, line 15. Regardless of Applicant's intent to refer to the formulated product or to its diclofenac component, Falk teaches application of either at a maximum level of less than 0.2 g/cm^2, therefore absorption must be less than 0.2 g/cm^2 because it cannot exceed the amount applied. Assuming Falk's product is applied over a 10 cm^2 area, amounting to 0.002 g (2 mg) diclofenac, and further assuming that all of this is absorbed systemically, this amounts to less than 3% of the smallest "recommended systemic daily unit dose" (75 mg), a fraction that might be considered by a person of ordinary skill in the art to indicate substantial non-absorption.

Regarding claim 16, Applicant recites a device comprising one or more components selected from a group that includes polysaccharides. Falk teaches use of the polysaccharide hyaluronic acid (Abstract), already a component of skin and well suited in terms of biocompatibility for this application.

Regarding claim 20, Applicant recites a device comprising ibuprofen as the "pain-killing agent." Falk is discussed above, further teaching the use of ibuprofen (2-[4-(2-methylpropyl)phenyl]propanoic acid, column 9, lines 30-35) as warranted for efficacy and patient tolerability.

Regarding claims 21-23, 25, 26, Falk is discussed above. Specifically, Falk teaches the use of a hyaluronic acid composition (inherently a hydrogel), which when applied to the wound surface, inherently "faces" the pain-killer delivery surface toward the wound surface. Application of Falk's gel in the specified amount of 20 mg/cm^2 of surface yields a "relatively thin" "sheet-like" layer that is 0.2 mm thick.[2]

Claims 24, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falk as applied to the claims above, and further in view of Chen (US 6,500,539).

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[2] Given that the formulation is largely water, a density of 1 g/mL (1 cm^3/g) is assumed for the formulation. (20 mg/cm^2 x 1 g/1000 mg x 1 cm^3/g x 10 mm/cm) = 0.2 mm

Falk is discussed above, but does not teach a device having non-stick properties with regard to the wound, nor does it teach a device in the form of a fabric coated or impregnated with a composition comprising the pain-killing agent.

Chen teaches a "fabric with non-adherent characteristics" comprising a "fiber having an anti-biologic incorporated in the fiber" (Abstract). The advantage associated with a fabric covering of the wound is that it affords a measure of protection to the wound that is not offered by a simple gel dressing. Accordingly, it would have been obvious to a person of obvious skill in the art at the time the invention was made to have combined the drug delivery capable fabric dressing of Chen with the anti-inflammatory delivering dressing of Falk in situations where protection and pain relief were desired.

Application Status and Examiner Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey S. Eberhard, Ph.D. whose telephone number is (571) 270-3289. The examiner can normally be reached from 7:00 am to 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Art Unit 1615

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